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ESTRADIOL AND PROGESTERONE IN IN VITRO FERTILIZATION (ESPRIT): EVALUATION OF THE THIRD VERSUS SECOND GENERATION ESTRADIOL AND PROGESTERONE ELECSYS_ ASSAYS.

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OBJECTIVE: To assess estradiol (E2) and progesterone (P) results taken during ovarian stimulation for IVF when determined by third (III) and second (II) generation (Gen) Elecsys_ assays.

DESIGN: ESPRIT was a retrospective, non-interventional study, in which blood samples were collected from patients on a GnRH-agonist/antagonist protocol who had a poor, normal or high (antagonist only) response to controlled ovarian stimulation, at two sites (UZB, n¼152, agonist and antagonist; IVI, n¼78, antagonist only). Samples were collected at 3-4 visits during the stimulation cycle, at time points reflecting the site's routine clinical practice.

MATERIALS AND METHODS: Women (18-45 years, BMI 18-35kg/m²) with regular menstrual cycles (25-35 days) and both ovaries present were classified as poor (n¼76), normal (n¼94), or high responders (n¼60) based on number of oocytes retrieved (0-3, 4-15, >15 respectively). Small, intermediate and mature follicle counts were recorded at each visit. E2 and P were measured in serum samples using the Elecsys_ E2 Gen II and Gen III, and Progesterone Gen II and Gen III assays. Regression parameters were assessed by Passing-Bablok.

RESULTS: Patient (n¼230) baseline characteristics were balanced; 62 patients received a GnRH agonist protocol and 168 an antagonist protocol. Elecsys_ Gen III and Gen II assay results were highly correlated for E2 (Pearson's r¼0.99) and P (Pearson's r¼0.89). For sites combined, the mean relative difference between E2 results (n¼801) determined with Gen III was -15.13% (SD¼13.22) compared with Gen II, whereas P results (n¼816) determined with Gen III were -43.31% (SD¼25.61) compared with Gen II. At day of triggering, Gen III E2 and P levels showed a difference of -14.98% and -27.89%, respectively. For 20 out of 36 patients with Gen II P levels >1.5 ng/mL, results for Gen III were concordant. However, 16 patients had a P level <1.5ng/mL with Gen III. Differences observed for E2 had minimal clinical relevance. E2 and P were shown to increase during controlled ovarian stimulation; the increases were greater in high responders versus poor or normal responders.

CONCLUSIONS: E2 and P levels determined with Elecsys_ Gen II and III assays were highly correlated. Results for both E2 and P were lower for Gen III versus Gen II. The differences observed for P at the day of triggering may be clinically relevant. Thus, clinicians

changing to the Elecsys_Progesterone III assay should be aware of the differences during clinical decisionmaking. Supported by: Funding: Roche Diagnostics